DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 5, 2014

CareFusion
Ms. Joy Greidanus
Regulatory Affairs Manager
75 North Fairway Drive
Vernon Hills, IL 60061

Re: K141552
Trade/Device Name: Achieve Programmable Automatic Biopsy Systems
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: Class II
Product Code: KNW
Dated: June 10, 2014
Received: June 11, 2014

Dear Ms. Greidanus:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved OMB No 0910-0120
Expiration Date January 31, 2017
See PRA Statement below

510(k) Number *(if known)*
K141552

Device Name

Achieve Programmable Automatic Biopsy System

Indications for Use *(Describe)*

Intended for use in obtaining core biopsy samples from soft tissue such as kidney, liver, prostrate, spleen, lymph nodes, and various soft tissue masses. Not intended for use in bone.

The Achieve Programmable Automatic Biopsy System is also indicated to provide breast tissue samples for diagnostic sampling of breast abnormalities. It is designed to provide breast tissue for histologic examination with partial or complete removal of the imaged abnormality.

The extent of histologic abnormality cannot be reliably determined from its mammographic appearance. Therefore, the extent of removal of the imaged evidence of an abnormality does not predict the extent of removal of a histologic abnormality (e.g., malignancy). When the sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal using standard surgical procedures.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs gov

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510(k) SUMMARY K141552

A summary of 510(k) safety and effectiveness information in accordance with 21 CFR 807.92.

SUBMITTER INFORMATION	
Name	CareFusion
Address	75 North Fairway Drive, Vernon Hills, IL 60061 USA
Phone number	(847) 362-8103
Fax number	(312) 949-0583
Establishment Registration Number	1423507
Name of contact person	Joy Greidanus
Date prepared	August 26, 2014
DESCRIPTION OF DEVICE	
Trade or proprietary name	Achieve Programmable Automatic Biopsy Systems
Common or usual name	Soft Tissue Biopsy Needle
Classification name	Instrument, Biopsy
Classification panel	Gastroenterology/Urology
Regulation	Class II per 21CFR §876.1075
Product Code(s)	KNW
Legally marketed device(s) to which equivalence is claimed	K960064 CareFusion Achieve (Formerly Bauer Medical) and K133948 Bard Monopty
Reason for 510(k) submission	Updates to labeling and device modifications.
Device description	The Achieve® Programmable Automatic Biopsy Systems are used to remove, by cutting, a specimen of tissue for microscopic evaluation. The organs in which the device may be used include but are not limited to breast, kidney, liver, prostate, spleen and lymph nodes plus various soft tissue masses. The device provides precise control and quality sampling capability when working with calcified or fibrous lesions. The lightweight system offers spring-loaded action for fast, accurate penetration of dense tissue.
Intended use of the device	The Achieve Programmable Automatic Biopsy System is intended for use in obtaining core biopsy samples from soft tissue such as kidney, liver, prostrate, spleen, lymph nodes, and various soft tissue masses. Not intended for use in bone. The Achieve Programmable Automatic Biopsy System is also indicated to provide breast tissue samples for diagnostic sampling of breast abnormalities. It is designed to provide breast tissue for histologic examination with partial or complete removal of the imaged abnormality. The extent of histologic abnormality cannot be reliably determined from its mammographic appearance. Therefore, the extent of removal of the imaged evidence of an abnormality does not predict the extent of removal of a histologic abnormality (e.g., malignancy). When the sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal using standard surgical procedures.

SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE		
Characteristic	**New Device**	**Predicates**
Mode of Action	Single Puncture and Multiple Samples	Same as predicates: K960064 CareFusion Achieve (Formerly Bauer Medical) and K133948 Bard Monopty
Firing modes	Automatic and Delay	Same as predicate: K960064 CareFusion Achieve
Anatomical Sites	Breast, kidney, liver, prostate, spleen, lymph nodes and various soft tissue masses	Same as predicate: K960064 CareFusion Achieve (Formerly Bauer Medical) and K133948 Bard Monopty
CONCLUSION OF DEVICE COMPARISON		
The technological characteristics of the proposed devices are substantially equivalent to the predicate.		
PERFORMANCE DATA		
SUMMARY OF NON-CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE		
Performance Test Summary		
Characteristic	Standard/Test/FDA Guidance	
Biocompatibility	AAMI/ANSI/ISO 10993-1:2009 Biological evaluation of Medical Devices Part 1: Evaluation and Testing	
Residuals	AAMI/ANSI/ISO 10993-7:2008 Biological evaluation of Medical Devices Part 7: Ethylene Oxide Sterilization Residuals	
Performance	BS EN ISO 9626:1995: Stainless Steel Needle Tubing for the Manufacture of Medical Devices.	
Performance	ISO 11737-1,2:2006 Sterilization of Medical Devices – Microbiological Methods	
Performance	ISO 11135:2007 Medical Device, Validation and Routine Control of Ethylene Oxide Sterilization	
Performance	ISO 11138:1 2006 Sterilization of Healthcare Products, Biological Indicators	
Performance	AAMI TIR28:2009 Product Adoption and Process Equivalency for Ethylene Oxide Sterilization	
Performance	ANSI/AAMI/ISO 11607:2006 Packaging for Terminally Sterilized Medical Devices	
Performance	ASTM F899-95 Standard Specification for Stainless Steel Billet, Bar and Wire for Surgical Instruments	
Performance	ASTM F1980-07 Accelerated Aging of Sterile Barrier Systems	
Performance	BS/EN/ISO 9626:1995 Stainless Steel Needle Tubing for the Manufacture of Medical Devices	
Performance	Biopsy Sample Testing – Comparison of samples obtained by predicate and proposed devices to prove equivalency.	
Performance	Weld Strength Testing – Verification of the proposed device stylet weld strength to ensure safety and effectiveness.	
Performance	Firing Speed Testing - Comparison of the firing speeds of the predicate and proposed devices to prove equivalency.	
Performance	Ultrasound Visibility Testing - Verification of the proposed device ultrasound visibility to ensure safety and effectiveness.	

SUMMARY OF CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE AND/OR OF CLINICAL INFORMATION
N/A – No clinical tests were conducted for this submission
CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA
The results of the non-clinical tests show the CareFusion Achieve Programmable Automatic Biopsy Systems meet or exceed all performance requirements, and are substantially equivalent to the predicate devices.